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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,837	08/02/2006	Michael Crothers	833.012	6054

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EXAMINER	
MI, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
09/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/550,837	**Applicant(s)** CROTHERS ET AL.	
	Examiner QIUWEN MI	**Art Unit** 1655	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 August 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *01 August 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *1-18*.
   Claim(s) withdrawn from consideration: *none*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Michael V. Meller/
Primary Examiner, Art Unit 1655

Continuation of 11. does NOT place the application in condition for allowance because:
The previous 102 rejections under Belanger or Breton are withdrawn as the cited references do not teach the effective amount of the adjuvant as in amended claims.
Regarding the 103 rejection, Applicant argues that there is no motivation to combine the references as the benefit of Modi is not needed for Breton composition (page 7, last paragraph bridging page 8).
This is not found persuasive. As indicated in the previous action, Breton et al do not teach paracellular pathway, encapsulation, and claimed amount of chitin/chitosan. Modi teaches protein drug was encapsulated in mixed micelles which allows opening of paracelular junctions with high degree of protease activity preserved and protecting molecules from premature degradation in the hostile acidic and proteolytic GI environment (in vivo), and overcoming the problem of the bitter taste and irritation of the drug (col 2, lines 58-67; col 3,lines 1-5). It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use the encapsulation technique to enhance the paracelular permeability of Modi in Breton et al since Modi teaches that the delivery system has high degree of protease activity preserved and it can protect molecules from premature degradation in the hostile acidic and proteolytic GI environment (in vivo), and it overcomes the problem of the bitter taste and irritation of the drug (col 2, lines 58-67; col 3, lines 1-5). Since the invention of Modi yielded beneficial results in drug delivery system, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional
working parameters (e.g., determining an appropriate amount of the components within the
composition) is deemed merely a matter of judicious selection and routine optimization which is
well within the purview of the skilled artisan.
Whether the protection of labile material and method of opening paracellular junction are separate issues or not (page 8, last paragraph), is not relevant to the 103 rejection.
In addition, as indicated previously, Molano et al was only brought in to show that chitin is distributed in yeast cell walls, and it has nothing to do with the tight junction function.
Regarding the Declaration filed on 8/1/2008, after the background introduction (1-10), Applicant's argument regarding the tight junction function (11) is not relevant, as the claims are drawn to a product, not a method, and tight junction function is not even the intended use of the claims. Applicant's argument regarding Belanger and Breton references (12 and 13) are not persuasive, as they are all about intended use of a product. Both BCA and PMSF are pharmaceutically active compounds, the reason the previous 102 rejections are withdrawn is because the cited references do not teach the effective amount of the adjuvant as currently amended. Regarding Modi, Applicant argues that the mixed micelle complexes in Modi are not sufficiently to reach the intestinal mucosa (14), it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's arguments in 15-17 have been addressed above.
Applicant's arguments have been fully considered but they are not persuasive, and therefore the 103 rejection in the record are maintained..